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14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN JOSE DIVISION

17 UNITED STATES OF AMERICA,
18 Plaintiff,
19 v.
20 RAMESH "SUNNY" BALWANI,
21 Defendant.

Case No. CR-18-00258-EJD

**MOTION TO STRIKE IMPROPER
EXPERT TESTIMONY AND OTHER
PROHIBITED TESTIMONY**

Date: April 1, 2022
Time: 8:30 a.m.
CTRM.: 4, 5th Floor

Hon. Edward J. Davila

MOTION TO STRIKE IMPROPER EXPERT TESTIMONY AND OTHER PROHIBITED TESTIMONY

PLEASE TAKE NOTICE that on April 1, 2022, at 8:30am, or on such other date and time as the Court may order, in Courtroom 4 of the above-captioned Court, located at 280 South First Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Ramesh “Sunny” Balwani will and hereby does respectfully move the Court to strike improper expert testimony and other prohibited testimony elicited by the government from Erika Cheung and Mark Pandori. The Motion is based on the below Memorandum of Points and Authorities, the Declaration of Jeffrey B. Coopersmith and attached exhibits, the record in this case, and any other matters that the Court deems appropriate.

DATED: March 31, 2022

Respectfully submitted,

ORRICK HERRINGTON & SUTCLIFFE LLP

By: /s/ Jeffrey B. Coopersmith
Jeffrey B. Coopersmith

Attorney for Defendant
RAMESH “SUNNY” BALWANI

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

In the opening weeks of trial, the government has elicited improper testimony from the first two witnesses: Erika Cheung and Mark Pandori. Both witnesses have testified based on specialized scientific and technical knowledge and training far beyond the bounds of permissible lay testimony. This testimony should be stricken; these witness were neither noticed nor qualified as experts as required by Rules 16(a)(1)(G) and 702. Certain parts of Dr. Pandori's testimony should also be stricken because it violated two of this Court's pretrial rulings: that (1) witnesses cannot offer impermissible legal opinions; and (2) lay witnesses cannot suggest that Theranos' modifications of third-party commercial devices were improper or akin to "tampering." Dkt. 1326 at 24.

II. ARGUMENT

A. The Court Should Strike Testimony by Ms. Cheung and Dr. Pandori That Relied on Specialized Training and Knowledge, But Was Not Noticed or Qualified as Expert Testimony

The line between lay and expert testimony is clear: When a witness testifies "based on *scientific, technical, or other specialized knowledge*," they are offering expert testimony. Fed. R. Evid. 701(c) (emphasis added); *see also* Fed. R. Evid. 701, advisory committee's note to 2000 amendment (expert testimony "results from a process of reasoning which can be mastered only by specialists in the field"); Fed. R. Evid. 702 (referring to a "witness who is qualified as an expert by knowledge, skill, experience, training, or education"). Thus, a physician testifying in a lay capacity—even if sufficiently trained and experienced to make a causal connection—cannot testify that "bruising around the eyes is indicative of trauma." Fed. R. Evid. 701 advisory committee's note to 2000 amendment.

Throughout Ms. Cheung's and Dr. Pandori's testimony, both witnesses testified to opinions that can only turn on specialized technical and scientific training and knowledge, including opining about the causes and implications of quality-control and proficiency-test results. For instance, Ms. Cheung testified that deviation on quality-control tests "was an indication that there was some issue in the accuracy of the actual device" that could affect patient

1 results, Trial Tr. 3/23/22 at 1202–03, because “if you [] extrapolate out essentially the percentage
 2 of failures that are happening across the system, ... [i]t seems likely that maybe there’s some
 3 issue with the chemistry,” *id.* at 1247–48.¹ But no percipient observation told her why the quality
 4 controls were failing, and she offered none. Ms. Cheung instead connected quality control failures
 5 in devices that would not be used for patient testing until they passed to hypothetical unreliability
 6 of patient testing run on only those machines that *passed* quality control. The government held
 7 her out as a quasi-expert, complete with undergraduate degree, to opine on the accuracy and
 8 reliability of results far beyond the scope of her employment as an entry-level lab associate.

9 Similarly, Dr. Pandori testified that quality-control failures were “emblematic of two
 10 possible problems from a diagnostic lab perspective, ... most importantly accuracy of the test
 11 being an issue[] [and] the reliability of the test.” Trial Tr. 3/30/22 at 1639; *see id.* at 1617
 12 (testifying that the “coefficient of variation” in quality-control runs is indicative of “the accuracy
 13 and precision of a test”). He also testified that the results of Theranos’ proficiency testing “called
 14 into question” “both accuracy and precision” of Theranos technology. *Id.* at 1650–51; *id.* at 1662
 15 (“compliance with PT testing serves a regulatory requirement, but it really is ... essential for an
 16 objective manner in assessing the quality and accuracy of your lab tests, and that serves a patient
 17 safety function”). But just as a physician cannot offer lay testimony that “bruising around the eyes
 18 is indicative of trauma,” Fed. R. Evid. 701 advisory committee’s note to 2000 amendment,
 19 Dr. Pandori and Ms. Cheung cannot offer lay testimony that quality-control and proficiency-test
 20 results were “indicative of” Theranos technology’s purported incapacity to produce accurate and
 21 precise test results that could undermine patient safety.

22 That a witness testifies based on their personal and professional knowledge, training, and
 23 experience does not immunize it from Rule 702. *United States v. Figueroa-Lopez*, 125 F.3d 1241,
 24 1246 (9th Cir. 1997) (“The mere percipience of a witness to the facts on which he wishes to
 25 tender an opinion does not trump Rule 702.”). In fact, the opposite is true: When a witness can
 26

27 ¹ The impermissible testimony cited in this motion, and other testimony that warrants striking for
 28 the same reasons, is attached and highlighted in Exhibit 1 to the attached Declaration by Jeffrey
 B. Coopersmith.

1 testify about a scientific or technical matter *because of* their unique training and experience, it is
 2 essential that the proponent establish the sufficiency and reliability of the witness’s knowledge
 3 and background—i.e., disclose and qualify the witness as an expert. *See* Fed. R. Evid. 701; Fed.
 4 R. Crim. P. 16(a)(1). Far from curing the issue, asking a witness “to answer questions ‘based
 5 upon [their] training and expertise” is a telltale sign that the questioner is calling for “observations
 6 requir[ing] demonstrable expertise” and compounds the prejudice. *Figueroa-Lopez*, 125 F.3d at
 7 1246 (example of law enforcement agent qualifying his personal observations as “based upon the
 8 training that he had at the DEA academy” and thus veering into the realm of expert testimony).

9 That is precisely what occurred with Ms. Cheung and Dr. Pandori. The government
 10 elicited testimony that required specialized training and knowledge to understand and explain
 11 scientific concepts and practices. And when confronted with Rule 702 objections, the government
 12 attempted to inoculate this expert testimony by establishing that it was based on the witnesses’
 13 specialized training and knowledge from their education, prior work experience, and work at
 14 Theranos—and the Court approved that approach. *E.g.*, Trial Tr. 3/22/22 at 1137–38 (reframing
 15 questions to Ms. Cheung and overcoming Rule 702 challenges by asking if her testimony was
 16 based on her “training and experience at the company” and derived from “what she was instructed
 17 and trained”); Trial Tr. 3/23/22 at 1247–48 (sanitizing question that had elicited expert testimony
 18 by asking whether the answer was “based on the training that [Ms. Cheung] got at Theranos”);
 19 Trial Tr. 3/30/22 at 1609 (laying foundation to overcome Rule 702 objection by establishing
 20 Dr. Pandori’s “experience working at clinical labs” and “knowledge of the industry”). That is
 21 exactly what the Ninth Circuit held impermissible in *Figueroa-Lopez*.

22 In fact, at several points, Dr. Pandori stated that his testimony was based on his familiarity
 23 with specialized literature, his experience and certification in diagnostic laboratory testing, and
 24 his expertise. *E.g.*, 3/30/22 Trial Tr. at 1610 (grounding testimony in his “familiarity” with the
 25 “literature”); *id.* at 1649 (noting that “[y]ou would need to be, you know, an expert to appreciate
 26 the differences [between the results of proficiency tests on predicate machines and on Theranos’
 27 proprietary technology] because those differences don’t look large but there’s large differences
 28 there”); *id.* at 1657 (explaining that “the raw data” he had reviewed to reach conclusions of

1 concern to him “would be done by somebody who has experience in diagnostic lab testing, ...
 2 maybe to some degree biostatistics”); *id.* at 1640 (drawing on his professional experience to
 3 testify that he was “used to a rate of [quality] control failure being ... in the 1 percent or less
 4 range”). At one point, Dr. Pandori **rejected** the foundational question the government offered and
 5 proclaimed outright that he was offering his opinions as a qualified expert:

6 Mr. Cazares: Objection. It calls for legal conclusion testimony.

7 The Court: Are you asking him his **knowledge of the scope of his employment?**

8 Mr. Bostic: Exactly, Your Honor. I’m happy to rephrase that.

9 The Court: Why don’t you. Thank you.

10 By Mr. Bostic:

11 Q: Dr. Pandori, **based on your understanding of your job responsibilities and the**
 12 **scope of your employment**, was it part of your responsibility to give your opinion
 13 and input on how proficiency testing was run at Theranos?

14 Mr. Cazares: 702.

15 The Court: Overruled.

16 The Witness: ***I wasn’t ever—I wasn’t entirely clear. I didn’t have a list of job***
 17 ***descriptions*** and that, so I took it upon myself to make sure that the lab was running
 18 properly in any way that I could. And ***because I had a lot of experience in directing***
 19 ***laboratory activities and looking at PT’s and I’m Board certified as a high***
 20 ***complexity laboratory director, I felt that I could contribute*** in a meaningful way
 21 to this conversation.

22 *Id.* at 1663–64 (emphasis added).

23 Ms. Cheung’s testimony was improper because she—a layperson without the requisite
 24 expertise—offered technical and scientific conclusions about the capabilities of Theranos
 25 technology “merely because [she] was an eyewitness to the” testing run on the equipment.
 26 *Figueroa-Lopez*, 125 F.3d at 1246; *see id.* (risk that a “layperson witnessing the removal of a
 27 bullet from a heart during an autopsy could opine as to the cause of the decedent’s death”).
 28 Ms. Cheung lacks the expertise to offer anything beyond percipient testimony on the technical
 capacity of Theranos technology. A recent college graduate at the time of her short tenure at
 Theranos, Ms. Cheung acknowledged the limits of her own training and experience. *See* Trial Tr.
 3/22/22 at 1117 (her job at Theranos was her “first job out of college”); *id.* at 1126 (“I was at the
 bottom of the sort of organizational chart”); Trial Tr. 3/30/22 at 1502 (she did not have expertise
 in the statistical adjustments made to raw data generated during proficiency testing); *id.* at 1507–
 08 (she did not understand that “the matrix effect” is one reason machines without a peer group
 can perform “alternative assessment protocol” in lieu of proficiency testing); *id.* at 1533 (she was

1 not an expert in the “Westgard rules” that “govern how labs are supposed to look at continuous
2 [quality control]”).

3 On the flip side, that a witness may be qualified to offer expert testimony does not absolve
4 the government of its obligation to disclose and offer the witness as such. *See* Fed. R. Evid.
5 16(a)(1)(G); Fed. R. Evid. 702. Dr. Pandori clearly testified as an expert. The prosecution began
6 his direct examination by eliciting details about his education, scientific training, professional
7 experience, and academic appointments. 3/30/22 Trial Tr. at 1591–92. And while answering
8 questions, Dr. Pandori repeatedly offered expansive explanations of technical concepts, their
9 significance, and the opinions he drew from applying those concepts to what he saw at Theranos.
10 For instance, after being asked about “what [he] saw at Theranos,” Dr. Pandori suggested that
11 “we explain proficiency testing” first, and then proceeded to explain the meaning of “proficiency
12 testing,” its status as “a regulatory requirement,” and what in his expert opinion—although not
13 qualified as such—is “the most important thing about proficiency testing.” Trial Tr. 3/30/22 at
14 1643–44; *see also id.* at 1616–17 (explaining the meaning of “coefficient of variation” and its
15 relationship to “the accuracy and precision of a test”); *id.* at 1648 (explaining the meaning of “a
16 predicate method” and why “one might feel very confident that a predicate method will give an
17 accurate result on a patient”); *id.* at 1668 (explaining “the term ‘instrument bias’” and why
18 another lab director concluded that “the instrument bias is exacerbated with the p-protocols”).

19 The Court has recognized its role “as a gatekeeper” to ensure that every expert opinion is
20 reliable and based on sound scientific methodology because “expert witnesses are intended to
21 help the jury understand the facts.” Dkt. 798 at 49. Dr. Pandori testified in just this sort of
22 educational capacity for the jury, even though he was never disclosed or qualified as an expert as
23 required. *See* Fed. R. Evid. 16(a)(1)(G); Fed. R. Evid. 702.

24 Ms. Cheung’s and Dr. Pandori’s testimony based on their specialized knowledge, training,
25 and experience was improper expert testimony by lay witnesses. It should be stricken.

26 **B. The Court Should Strike Testimony by Dr. Pandori That Offered**
27 **Impermissible Legal Opinions**

28 In deciding the parties’ motions in limine, the Court ruled that the government “cannot

1 offer evidence detailing violations of industry standards or government regulations solely to
 2 support an element of the charged offense, but that statements made to [Mr. Balwani] concerning
 3 perceived violations of industry standards and government regulations [are] admissible” for the
 4 limited purpose of showing “notice was given to [Mr. Balwani] and [his] state of mind.”
 5 Dkt. 1326 at 24 (applying ruling from Dkt. 798); *see Lukov v. Schindler Elevator Corp.*,
 6 No. 5:11-cv-00201 EJD, 2012 WL 2428251, at *2 (N.D. Cal. June 26, 2012) (testimony “couched
 7 ... in the form of a legal conclusion[] ... is improper and must be excluded”). Mr. Balwani is not
 8 charged with violating industry standards or CLIA regulations. Thus, it is inappropriate for
 9 witnesses to testify that Theranos violated standards and regulations per se, with no connection to
 10 Mr. Balwani’s awareness or state of mind.

11 Still, during the direct examination of Dr. Pandori, the government elicited testimony
 12 about the requirements and purposes of CLIA regulations untethered to the restriction the Court
 13 set in Dkt. 1326. For instance, Dr. Pandori testified that “the regulations are very clear at the
 14 federal level and most state levels that proficiency testing has to be done in a manner identical to
 15 the way that patient tests are treated.” 3/30/22 Trial Tr. at 1645. And the purpose of these
 16 regulations, he testified, is to “serve[] a patient safety function.” *Id.* at 1662. This is classic
 17 improper legal opinion. *See Lukov*, 2012 WL 2428251, at *2 (excluding testimony that was
 18 “ostensibly based on what appears to be [the witness’s] own survey of state laws”).

19 The government sometimes tied Dr. Pandori’s legal opinions to Mr. Balwani’s state of
 20 mind. 3/30/22 Trial Tr. at 1659–61 (noting Mr. Balwani’s inclusion on email about how to be in
 21 “full compliance with the regs”). But the government then violated this Court’s ruling and Ninth
 22 Circuit precedent by asking Dr. Pandori what the law objectively means. When questioning Dr.
 23 Pandori about an email in which Ms. Holmes said that “it is critical that no one is guessing on
 24 [regulatory] matters like these,” the government asked Dr. Pandori: “were you guessing about the
 25 [regulatory] requirements?” 3/30/22 Trial Tr. at 1661. His answer was definitive: “No.” *Id.* The
 26 jury was left with the impression that Dr. Pandori knows the objective meaning of the regulations
 27 and how exactly they apply to Theranos’ novel technology. Not only was the jury encouraged to
 28 rely on Dr. Pandori’s improper legal opinions, the jury could now find that the government has

1 proven an element of the charged offense—that Theranos’ technology was incapable of
 2 producing accurate and reliable results and/or that Mr. Balwani had the requisite criminal intent—
 3 based solely on violations of industry standards and government regulations. This is the very risk
 4 that the Court’s pretrial ruling was designed to avoid. Dkt. 1326 at 24. This testimony should be
 5 stricken.

6 **C. The Court Should Strike Testimony by Dr. Pandori That Theranos “Hacked”**
 7 **Third-Party Commercial Devices and Instruct the Jury Not to Infer That**
 8 **Modifications to Such Devices Were Improper**

9 Finally, the Court should strike another portion of Dr. Pandori’s testimony that violated
 10 another of the Court’s pretrial rulings: that the government cannot “suggest the third-party
 11 platforms [i.e., commercial devices] were ‘tampered’ with until and unless that has been proven
 12 by appropriate evidence,” such as qualified expert testimony. Dkt. 1326 at 29; dkt. 798 at 67
 13 (“The Government has not presented any opinions from qualified experts under Rule 702 to
 14 establish whether and to what extent certain modifications to third-party testing platforms may be
 15 considered ‘tampering.’”). When asked about Theranos devices, Dr. Pandori testified that “there
 16 was a version of the FDA cleared machine, and that some people at the company called it hacked,
 17 H-A-C-K-E-D.” 3/30/22 Trial Tr. at 1606. He repeated this loaded term later in his testimony. *Id.*
 18 at 1665 (“There were problems with the hacked equipment as well.”).

19 Dr. Pandori’s description (which was also based on hearsay) insinuated that Theranos’
 20 modifications to the third-party devices were improper, unethical, and even illegal. *See Hack*,
 21 Miriam-Webster.com, <https://www.merriam-webster.com/dictionary/hack> (last visited March 31,
 22 2022) (including among definitions “to gain illegal access to (a computer network, system,
 23 etc.)”). These implications are even worse than those suggested by the word “tampering,” which
 24 the Court specifically precluded. Dkt. 1326 at 29; *see Tamper*, Miriam-Webster.com,
 25 <https://www.merriam-webster.com/dictionary/tamper> (last visited March 31, 2022) (“to interfere
 26 so as to weaken or change for the worse”). Worse, the government was on notice that Dr. Pandori
 27 might use this term to describe the modified devices because he did so during his March 22, 2022
 28 interview with the government in preparation for his testimony. *See Declaration of Jeffrey B.*
Coopersmith ¶ 3 & Exhibit 2. The government’s apparent failure to instruct Dr. Pandori on this

1 Court's Order is troubling. *See United States v. Chen*, No. 17-cr-000603-BLF-1, 2021 WL
 2 2662116, at *9 (N.D. Cal. June 29, 2021) (denying defense motion in limine to implement the
 3 court's prior orders as unnecessary and observing that "[a]ll parties are required to follow the
 4 Court's orders and instruct their witnesses to do the same").

5 Dr. Pandori's impermissible testimony that third-party devices were "hacked" should be
 6 stricken. The Court should also instruct the jury not to infer that Theranos' modifications to third-
 7 party devices were in any way improper, unethical, or illegal, as no such foundation has been laid.

8 **III. CONCLUSION**

9 The Court should grant Mr. Balwani's motion and (i) strike all impermissible expert
 10 testimony by Ms. Cheung and Dr. Pandori; (ii) strike any testimony that violates the Court's
 11 pretrial rulings prohibiting both legal opinions and suggestions that Theranos "tampered with"
 12 third-party commercial devices; and (iii) instruct the jury not to infer that Theranos' modifications
 13 to third-party commercial devices were improper.

14
 15 DATED: March 31, 2022

Respectfully submitted,

16 ORRICK HERRINGTON & SUTCLIFFE LLP

17
 18 By: /s/ Jeffrey B. Coopersmith
 Jeffrey B. Coopersmith

19 Attorney for Defendant
 20 RAMESH "SUNNY" BALWANI